IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PBG PUERTO RICO LLC, and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
	)	C.A. No. 19-517 (LPS)
v.	)	
AJANTA PHARMA LTD. and AJANTA PHARMA USA INC.,	)	
Defendants.	)	

AMENDED COMPLAINT

Pfizer Inc., PF PRISM C.V., C.P. Pharmaceuticals International C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (collectively "Plaintiffs" or "Pfizer"), for their Amended Complaint against Ajanta Pharma Ltd. and Ajanta Pharma USA Inc. (collectively "Ajanta"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Ajanta for infringement of United States Patent No. 6,965,027 (the "'027 patent") and United States Reissue Patent No. RE41,783 (the "RE'783 patent").

2. This action arises out of Ajanta's submission of Abbreviated New Drug Application ("ANDA") No. 212943 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 5 mg and 10 mg Xeljanz® (tofacitinib) tablets ("Xeljanz Tablets") prior to the expiration of the '027 and RE'783 patents. The proposed Ajanta ANDA products are referred to hereinafter as "Ajanta Generic Tablets."

THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

5. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

6. Plaintiff PBG Puerto Rico LLC is a limited liability company organized and existing under the laws of Puerto Rico and having its principal place of business at Professional Offices Park V, 996 San Roberto Street, 4th Floor, San Juan, Puerto Rico 00926. Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

7. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) under Dutch law, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered with the Dutch Trade Register under number 60558814. Pfizer Inc. is the ultimate parent company of PF PRISM IMB B.V.

8. On information and belief, defendant Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at No. 98,

Ajanta House, Government Industrial Area, Charkop, Kandivali (West) Mumbai, Maharashtra 400067 India.

9. On information and belief, defendant Ajanta Pharma USA Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at One Grande Commons, 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807. On information and belief, Ajanta Pharma USA Inc. is a wholly-owned subsidiary of Ajanta Pharma Ltd. On information and belief, Ajanta Pharma USA Inc. is the U.S. agent for Ajanta Pharma Ltd.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Defendants have consented to this Court's jurisdiction for the purposes of Plaintiffs' claims against Defendants in this case.

12. Defendants have consented to venue in this district.

BACKGROUND

Pfizer's Xeljanz Tablets

13. Pfizer's Xeljanz Tablets are indicated for: the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate; the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs; or the treatment of adult patients with moderately to severely active ulcerative colitis.

14. Xeljanz Tablets contain tofacitinib citrate in an amount equivalent to 5 mg or 10 mg of tofacitinib base. The active ingredient in Xeljanz Tablets, tofacitinib, is a Janus kinase (JAK) inhibitor.

15. The FDA-approved Prescribing Information for Xeljanz Tablets states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile,2-hydroxy-1,2,3-propanetricarboxylate (1:1).

Orange Book Listing for Xeljanz Tablets

16. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for Xeljanz Tablets.

17. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '027 and RE'783 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the NDA No. 203214.

18. The Orange Book lists the expiration dates for the '027 patent as March 25, 2023, and the RE'783 patent as December 8, 2025.

19. The Orange Book also lists five additional patents for Xeljanz Tablets that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); 7,301,023 (expiring May 23, 2022), and 7,842,699 (expiring December 8, 2020).

The '027 Patent

20. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-

propionitrile citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit A.

21. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '027 patent.

22. C.P. Pharmaceuticals International C.V. conveyed rights under the '027 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A.

23. Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

24. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. conveyed its rights under the '027 patent to PF PRISM IMB B.V.

25. Pfizer Pharmaceuticals LLC conveyed its rights under the '027 patent to PBG Puerto Rico LLC.

The RE'783 Patent

26. On September 28, 2010, the USPTO issued the RE'783 patent, titled "Pyrrolo[2,3-D]pyrimidine Compounds." The RE'783 patent is a reissue of U.S. Patent No. 6,627,754, which issued on September 30, 2003. The RE'783 patent is duly and legally assigned to Pfizer Inc. A copy of the RE'783 patent is attached hereto as Exhibit B.

27. On December 14, 2016, the USPTO issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

28. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the RE'783 patent.

29. C.P. Pharmaceuticals International C.V. conveyed its rights under the RE'783 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A.

30. Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

31. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. conveyed its rights under the RE'783 patent to PF PRISM IMB B.V.

32. Pfizer Pharmaceuticals LLC conveyed its rights under the RE'783 patent to PBG Puerto Rico LLC.

Ajanta's ANDA No. 212943

33. By letter dated February 4, 2019 and received by Pfizer on February 5, 2019, Ajanta notified Pfizer that it had submitted ANDA No. 212943 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell generic 5 mg tofacitinib tablets prior to the expiration of the '027 and RE'783 patents. By letter dated July 24, 2019 and received by Pfizer on July 26, 2019, Ajanta notified Pfizer that it had amended ANDA No. 212943 to seek approval under the FDCA to market and sell generic 10 mg tofacitinib tablets prior to the expiration of the '027 and RE'783 patents. The February 4, 2019 and July 24, 2019 letters are collectively referred to herein as the "Ajanta Notice Letters."

34. The Ajanta Notice Letters assert that ANDA No. 212943 contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(1) and (j)(2)(A) alleging that each of the '027 and RE'783 patents "are invalid, unenforceable and/or will not be infringed by" Ajanta Generic Tablets.

35. The Ajanta Notice Letters state that Ajanta Generic Tablets will contain tofacitinib citrate as the active ingredient.

36. The Ajanta Notice Letters state that ANDA No. 212943 requests "approval to engage in the commercial manufacture, use or sale of" Ajanta Generic Tablets prior to the expiration of the '027 and RE'783 patents.

37. Attached to the Ajanta Notice Letters were Detailed Statements asserting the purported factual and legal bases for Ajanta's contention that the '027 and RE'783 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Ajanta Generic Tablets.

38. Ajanta's Detailed Statements allege that all claims of the '027 and RE'783 patents are invalid. Ajanta's Detailed Statements do not contain a noninfringement argument with respect to the '027 and RE'783 patents, other than that all claims are invalid.

39. On information and belief, Ajanta Pharma Ltd. and Ajanta Pharma USA Inc. collaborated and acted in concert in the decision to prepare and submit and in the preparation and submission of ANDA No. 212943.

40. On information and belief, upon approval of ANDA No. 212943, Ajanta will distribute Ajanta Generic Tablets throughout the United States.

COUNT I
(Infringement of the '027 Patent)

41. The allegations of paragraphs 1-40 above are repeated and re-alleged as if set forth fully herein.

42. Pursuant to 35 U.S.C. § 271(e)(2)(A), Ajanta's submission of ANDA No. 212943 seeking approval to market Ajanta Generic Tablets was an act of infringement of one or more claims of the '027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 212943 be a date which is not earlier than the expiration date of the '027 patent.

43. Ajanta had knowledge of the ’027 patent when it submitted ANDA No. 212943 to the FDA.

44. On information and belief, upon FDA approval, Ajanta intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Ajanta Generic Tablets and will thereby infringe at least claim 1 of the ’027 patent.

45. The foregoing actions by Ajanta constitute and/or would constitute infringement of at least claim 1 of the ’027 patent.

46. Pfizer will be substantially and irreparably harmed if Ajanta is not enjoined from infringing the ’027 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the RE’783 Patent)

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Ajanta’s submission of ANDA No. 212943 seeking approval to market Ajanta Generic Tablets was an act of infringement of one or more claims of the RE’783 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 212943 be a date which is not earlier than the expiration date of the RE’783 patent.

49. Ajanta had knowledge of the RE’783 patent when it submitted ANDA No. 212943 to the FDA.

50. On information and belief, upon FDA approval, Ajanta intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Ajanta Generic Tablets and will thereby infringe at least claim 1 of the RE’783 patent.

51. The foregoing actions by Ajanta constitute and/or would constitute infringement of at least claim 1 of the RE'783 patent.

52. Pfizer will be substantially and irreparably harmed if Ajanta is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Ajanta's submission of ANDA No. 212943 was an act of infringement and that Ajanta's making, using, offering to sell, selling or importing Ajanta Generic Tablets prior to the expiration of the '027 and RE'783 patents will infringe each of those patents;

B. A judgment that the effective date of any FDA approval for Ajanta to make, use, offer for sale, sell, market, distribute, or import the Ajanta Generic Tablets be no earlier than the dates on which the '027 and RE'783 patents expire, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining Ajanta, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering for sale, marketing, distributing, or importing Ajanta Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '027 and RE'783 patents, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

E. An award of Pfizer's costs and expenses in this action; and

F. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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